

REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein amendment and remarks, which place the application in condition for allowance.

Applicants thank the Examiner for indicating that the objection to the claims and the rejection of the claims under 35 U.S.C. § 103(a) are withdrawn.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 11-13, 16-18, and 34-37 are currently under consideration. Claims 35 and 37 are amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

The amendment to claims 35 and 37 are to clarify the claimed cells. Support for the amendment can be found throughout the specification as originally filed, for example, in the paragraph bridging pages 3 and 4. No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. § 112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that these amendments should not give rise to any estoppel, as they are not narrowing amendments.

II. THE DOUBLE PATENTING REJECTION IS PROVISIONAL

Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 11, 15-17, and 19 of copending U.S. application Serial No. 11/031,417.

Applicants reiterate that the issue of whether there is indeed double patenting is contingent upon the allowed subject matter in both applications. Applicants thereby request that the double patenting rejection be withdrawn or at least held in abeyance until allowable subject matter in both applications is determined. If, upon agreement as to allowable subject matter, it is

believed that there is still a double patenting issue, a Terminal Disclaimer as to U.S. application Serial No. 11/031,417 will be considered.

III. THE REJECTIONS UNDER 35 U.S.C. § 112 ARE OVERCOME

Deposit Requirement

Claims 35 and 37 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification to enable the skilled artisan to make and/or use the invention. In particular, the Office Action contended that deposits for cell lines TDF-2A bcl-2, TCF-4.10, and TCF-4.10 bcl-2 are not in full compliance with 37 C.F.R. §§ 1.803-1.809.

Applicants draw attention to the accompanying Declaration Regarding Availability of Biological Organisms, which states that the criteria recited in the Office Action pertaining to the availability of feline calicivirus strains have been met. Accordingly, reconsideration and withdrawal of the Section 112 rejection is respectfully requested.

Written Description

Claims 11-13, 16-19, and 34-37 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. This rejection is respectfully traversed.

The Office Action contended that while cell lines TDF-2A, TDF-2A bcl-2, TCF-4.10, and TCF-4.10 bcl-2 recited in the claims meet the written description provision of Section 112, the untransformed, immortalized avian cell comprising a nucleic acid encoding SV40T+t and an anti-apoptotic protein does not meet the written description requirement. Applicants respectfully disagree.

Applicants respectfully assert that there is substantial written description in the specification to support the instant claims. For example, the specification amply describes a structure-function relationship in the claimed avian cells. In particular, the claim recites that the genome of the claimed cells comprises a nucleic acid molecule encoding SV40 T+t, and the cell contains a nucleic acid molecule encoding an antiapoptotic protein. Notably, the skilled artisan would recognize the correlation between this structure and the functions of having an immortalized and untransformed phenotype and expressing an antiapoptotic protein. The specification indicates an association between the early t and T genes of the simian virus SV40

and immortalizing cells (*see, e.g.*, page 2, lines 5-32). Hence the structure-function relationship of the claimed invention is clear in light of the description in the specification.

Moreover, Applicants submit that the present invention showed that, for the first time, immortalized, untransformed avian cells comprising a nucleic acid molecule encoding SV40 T+t, and containing and expressing a nucleic acid molecule encoding an antiapoptotic protein. Prior to the present invention, the art had not taught or contemplated the use of SV40 T+t to obtain immortalized, untransformed avian cells. Therefore, even if immortalization of avian cells were difficult to achieve and would dissuade the skilled artisan from trying the present invention, the specification demonstrated how it can be achieved using SV40 T+t. Similarly, while there may be an association between SV40 T+t and transformation of cells which would deter the skilled artisan from using SV40 T+t, the specification showed untransformed avian cells comprising a nucleic acid encoding SV40 T+t. Therefore, one of ordinary skill in the art would recognize that the specification amply describes and supports the claimed invention.

Thus, the claims are compliant with the written description requirement.

Enablement

Claims 11-13, 16-19, 34, and 36 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. This rejection is respectfully traversed.

Applicants assert that one skilled in the art can practice the claimed invention without undue experimentation. Firstly, Applicants submit that the specification provides ample guidance and direction for the claimed cells, notably on page 3, lines 4-14, and page 4, lines 27-38. Further, Applicants draw attention to the working examples, which demonstrate how to produce the claimed untransformed, immortalized, avian cell wherein the genome of the cell comprises a nucleic acid molecule encoding SV40 T+t, and wherein the cell contains and expresses a nucleic acid molecule encoding an anti-apoptotic protein. In particular, Examples 1 and 3 demonstrate the production of the claimed avian cells comprising a nucleic acid molecule encoding SV40 T+t, and provide how tests can be performed to ascertain that they are immortalized and absent of tumorigenic capacity. Example 5 demonstrates integration of a nucleic acid molecule encoding an anti-apoptotic protein into the cells. Hence, the skilled artisan can practice the claimed invention from the disclosures in the specification.

Applicants additionally point out that one of ordinary skill in the art can practice the full scope of the instant claims in view of the teachings in the specification. For example, Example 3 demonstrates how to produce untransformed, immortalized cells comprising a nucleic acid molecule encoding SV40 T+t. Moreover, Example 5 demonstrates how to incorporate the anti-apoptotic bcl-2 gene into the untransformed, immortalized avian cells. The skilled artisan would also be able to practice the claimed invention to produce cells comprising the full scope of anti-apoptotic genes.

Applicants reiterate that the claimed invention is to first to demonstrate that immortalized, untransformed avian cells comprising a nucleic acid molecule encoding SV40 T+t, and containing and expressing a nucleic acid molecule encoding an antiapoptotic protein, can be obtained. As described above, the specification demonstrated how immortalized avian cells and untransformed cells comprising a nucleotide molecule encoding SV40 T+t can be obtained, even if the state of the art prior to the present invention would deter one skilled in the art from trying. Therefore, the skilled artisan would not require undue experimentation to arrive at the claimed invention.

The instant claims are thereby enabled by the specification.

Indefiniteness

Claims 35 and 37 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Office Action contended that the phrase “derived from the cell line . . .” is vague and indefinite as to what constitutes a “derivation.”

In response, Applicants draw attention to the instant claims, wherein claims 35 and 37 indicate that the claimed cells are “progeny of” the recited cell lines, thereby further defining the claimed cells.

Accordingly, Applicants request reconsideration and withdrawal of all rejections under Section 112.

CONCLUSION

This application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: Thomas J. Kowalski by Russell A. Garman

Thomas J. Kowalski

Reg. No. 32,147

Russell A. Garman

Reg. No. 62,419

Tel: (212) 588-0800

Fax: (212) 588-0500